REMARKS

Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks. Claims 1-25 are pending and currently under examination in the application. Claims 1, 11, 20, 21, 22, and 23 are amended to more particularly point out and distinctly claim certain embodiments of Applicant's invention, and new claim 26 is added to correct an obvious clerical error. No new matter is added by the amendments. Support for the amendments can be found in the specification as filed, for example, in paragraph [0031], paragraph [0034], the title above paragraph [0048], and paragraph [0054]. It should be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Claim Objections

A. The Examiner objects to claim 22 under 37 C.F.R. § 1.75(c) for allegedly being in improper form and notes that claim 22 has not been further examined on the merits.

Applicant submits that the apparent multiple dependent form of claim 22 merely represents a clerical error. Specifically, the recitation "[t]he method of claim 6, wherein the achaogen is a small molecule, capable of inactivating one or more genes selected from the group consisting of PolB, DinB, UmuDC, and LexA" was intended to represent an entirely distinct claim. Accordingly, this recitation is deleted from claim 22, and is presently found in new claim 26. In view of this amendment, Applicant respectfully requests withdrawal of this objection.

B. The Examiner objects to claim 11 under 37 C.F.R. § 1.75(c), asserting that this claim fails to further limit the subject matter of the claim from which it depends. The Examiner contends, for example, that claims 1 and 11 both relate to selling a compound with an achaogen.

Applicant submits that the amendment to claim 11 obviates this objection. Claim 11 is amended to depend directly from claim 10 only, and, thus, no longer depends directly from

claim 1. As such, claim 11 further defines the scope of both claims 1 and 10 by reciting that *the biopharmaceutical company* of claim 10 sells said achaogen and said compound. In view of this amendment, Applicant respectfully requests withdrawal of this objection.

Rejections Under 35 U.S.C. § 101

The Examiner rejects claims 1-25 under 35 U.S.C. § 101 for being allegedly directed to non-statutory subject matter. The Examiner asserts that the claimed subject matter is neither tied to a statutory class nor transforms underlying subject matter to a different state or thing.

Applicant traverses this rejection and submits that the instant claims satisfy the patentability requirements under 35 U.S.C. § 101. In particular, Applicant respectfully disagrees with the Examiner's reliance on the assertion that the presently claimed process is neither tied to another statutory class nor transforms underlying subject matter. Rather, Applicant submits that the presently claimed process transforms a given antibiotic from a compound having decreased commercial or therapeutic potential to a compound having significant commercial and therapeutic potential, thereby producing a "useful, concrete and tangible result" in the marketplace and in public health. *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 1373, 1374, (Fed. Cir. 1998).

The present invention relates, in pertinent part, to a business method comprising: identifying a compound that is effective as an antibiotic; (i) determining if bacteria develop resistance to said compound whereby said compound would have decreased market potential because of, at least in part, said resistance; (ii) identifying an achaogen that is capable of decreasing the rate at which said bacteria mutates; and (iii) selling said compound with said achaogen. This claimed process produces a useful, tangible, concrete result in the market place. For example, the presently claimed process may "rescue" from commercial obscurity either a failed pre-clinical trial antibiotic candidate or an already approved, but commercially undesirable, antibiotic. In these exemplary situations, a given antibiotic may have failed pre-clinical trials or may have been considered commercially undesirable, because bacteria rapidly developed resistance to the antibiotic. Such an antibiotic would clearly have decreased market

potential, as recited in the instant claims. By identifying such an antibiotic, identifying an achaogen that decreases the rate at which bacteria mutate in response to the antibiotic, and selling the antibiotic with the agent, thereby reducing the rate of resistance to the antibiotic, the presently claimed process makes available to business entities, hospitals, physicians, and the public an antibiotic that would otherwise have been considered unmarketable for business reasons.

The presently claimed process also produces a useful, tangible, concrete result in public health. For one, by "rescuing" certain antibiotics from commercial obscurity, as above, common sense dictates that this process provides physicians with a more diverse array of antibiotics to combat the growing problem of antibiotic resistant bacterial infections. In addition, the combined sale of an achaogen and an antibiotic provides beneficial therapeutic effects in both individual patients and populations of patients. At an individual level, the combined sale of an achaogen and an antibiotic may prevent bacterial resistance in that patient, thereby improving the odds of a positive clinical outcome. At the population level, the combined sale can reduce the level of antibiotic resistance in that population, and, thus, increase the usefulness of antibiotics in general (*see, e.g.,* paragraph [0076] of the specification). By reducing the development of resistance to a given antibiotic in every day use, the presently claimed process transforms a selected antibiotic from a compound having decreased market and therapeutic potential into a compound having significant market and therapeutic potential. Thus, this process produces a useful, tangible, concrete result in the marketplace and in public health – the increased utility of an antibiotic.

As illustrated by these examples, Applicant submits that the presently claimed process represents more than just an abstract idea, but, rather, clearly sets forth a practical application to produce "real-world results" in the marketplace and in public health. *See Gottschalk v. Benson*, 409 U.S. 63, 71, 72 (1972). Given this practical application, in addition to the useful, real world results obtainable therefrom, Applicant submits that the instant claims satisfy the patentable subject matter requirements under 35 U.S.C. § 101, and respectfully requests withdrawal of this rejection.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejects claim 11 under 35 U.S.C. § 112, presumably under the second paragraph of this section, asserting that the recitation "said biopharmaceutical company" lacks antecedent basis.

Applicant traverses this rejection and submits that the instant claims satisfy the requirements under 35 U.S.C. § 112. Specifically, claim 11 is amended to depend directly from claim 10, and, thus, no longer depends directly from claim 1. The recitation "*said* biopharmaceutical company" in claim 11 finds antecedent basis in the recitation "a biopharmaceutical company" in claim 10, obviating this rejection. Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112.

Rejections Under 35 U.S.C. § 103

A. Claims 1, 11, 13-16, 20, 21, 23, and 24 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Hergenrother *et al.* (U.S. Application No. 2003/0130169). The Examiner asserts that Hergenrother *et al.* teach the step of identifying an antibiotic compound and determining if a bacteria develops resistance to said compound, and further asserts that this reference teaches administering said compound with an achaogen. The Examiner concedes that Hergenrother *et al.* fail to explicitly disclose the step of selling the compound with the achaogen, but asserts that it would have been obvious to sell an achaogen with a compound to make them accessible to the public.

Applicant respectfully traverses this rejection and submits that the instant claims satisfy the requirements of non-obviousness over Hergenrother *et al.* In particular, Applicant submits that the Examiner has not established a *prima facie* case of obviousness with respect to the presently claimed subject matter. *See In re Mayne*, 104 F.3d 1339 (Fed. Cir. 1997) (The USPTO has the burden of showing a *prima facie* case of obviousness). At a minimum, it must be positively demonstrated that the combined references teach or suggest all the claim features, and even assuming, *arguendo,* that the combination of references teaches each claim feature, the Action must provide an explicit, apparent reason to combine these features in the fashion claimed by the Applicant with a reasonable expectation of success. *See KSR v. Teleflex, Inc.,* No

04-1350 at 4, 14 (U.S. Apr. 30, 2007) ("A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art"). Here, Hergenrother *et al.* does not teach or suggest identifying an achaogen that is capable of decreasing the rate at which a bacteria mutate***s***, and selling an antibiotic compound with the achaogen, let alone does Hergenrother *et al.* provide the requisite motivation and reasonable expectation of success in arriving at the presently claimed process.

Applicant submits that Hergenrother *et al.* fail to teach or suggest each active, recited step of the instant claims, and in particular fail to teach or suggest the recited step of identifying an achaogen that is capable of decreasing the rate at which a bacteria mutates. Instead, as noted by the Examiner, Hergenrother *et al.* merely describe compounds that mimic plasmid incompatibility in bacteria, the use of which leads to the loss of bacterial plasmids otherwise responsible for antibiotic resistance. The compounds of Hergenrother *et al.*, however, have no effect on the ***rate*** at which a bacteria mutates, *i.e.,* an achaogenic effect, as presently claimed. Indeed, Hergenrother *et al.* do not in any way suggest the existence of such achaogenic compounds, let alone do they suggest that such compounds may be utilized to decrease antibiotic resistance, such as by selling the achaogen with an antibiotic. In this respect, the approach described by Hergenrother *et al.* is fundamentally different than the presently claimed methods, since the methods described by Hergenrother *et al.* target plasmids that mediate resistance, wherein the presently claimed methods target bacterial proteins that mediate mutation.

Moreover, Applicant respectfully disagrees with the Examiner's assertion that the type of achaogen represents "nonfunctional descriptive material" (*see* the Action, page 5). Applicant submits instead that the PTO must consider all claim features when determining patentability of an invention over the prior art. *In re Lowry*, 32 F.3d 1579, 32 (Fed. Cir. 1994). Further, all claim features must be considered meaningful. *D.O.C.C. Inc. v. Spintech Inc.*, 93 Civ. 4679, 36 U.S.P.Q.2d 1145, 1151 (N.Y. 1994). Here, the recited achaogens are capable of decreasing the rate at which a bacteria mutates, and include, for example, achaogens that modulate the activity of one or more genes selected from PolB, DinB, UmuDC, and LexA, as recited in dependent claim 21. As noted above, Hergenrother *et al.* fail to even remotely contemplate an achaogen that is capable of decreasing the rate at which a bacteria mutates, such

that, contrary to the Examiner's assertion, the methods of Hergenrother *et al.* are not at all "capable of using or selling the recited achaogens" of the instant claims (*see* the Action, page 5). Hergenrother *et al.*, therefore, fail to teach or suggest all of the active, recited step of the instant claims.

In addition, Hergenrother *et al.* fail to motivate a person of ordinary skill in the art to identify an achaogen that is capable of decreasing the rate at which a bacteria mutates, and sell an antibiotic compound with the achaogen, with any expectation of success, let alone with the requisite reasonable expectation of success. Rather, as noted above, Hergenrother *et al.* contain no hint or suggestion as to identifying an achaogen that is capable of decreasing the rate at which a bacteria mutates, and selling an antibiotic compound with the achaogen. Instead, given the deficiencies in Hergenrother *et al.*, a person of ordinary skill in the art would have to embark on a whole new line of experimentation to identify an achaogen that is capable of decreasing the rate at which a bacteria mutates, the motivation or guidance for which cannot be found anywhere in the evidence of record, including Hergenrother *et al.*

In view of this deficiency, Applicant respectfully points out that the burden of proof is on the Examiner to establish by technical reasoning that a person of ordinary skill in the art would have been motivated to practice the presently claimed subject matter with a reasonable expectation of success. *KSR* at 14, citing *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). Here, the Examiner provides no technical reasoning whatsoever to support the requisite motivation and reasonable expectation of success in starting with the method of Hergenrother *et al.* and arriving at the presently claimed process.

Moreover, given that Hergenrother *et al.* merely teach the identification of compounds that mimic plasmid incompatibility in a bacteria, the apparent modification proposed by the Examiner to identify an achaogen that is capable of decreasing the rate at which a bacteria mutates would clearly change the principle of operation of the teachings in this reference. In such a circumstance, the teachings of the reference are not sufficient to render the claims *prima facie* obvious. M.P.E.P. § 2143.01, citing *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (The

"suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate."). Since, as noted above, a person of ordinary skill in the art would have to completely redesign the elements of Hergenrother *et al.*, as well as change the basic principle under which this reference operates, to identify an achaogen that is capable of decreasing the rate at which a bacteria mutates, Hergenrother *et al.* fail to render the instant claims *prima facie* obvious.

Applicant submits that claims 1, 11, 13-16, 20, 21, 23, and 24 satisfy the requirements of obviousness over Hergenrother *et al.*, and respectfully requests withdrawal of this rejection under 35 U.S.C. § 103(a).

B. Claims 2, 3, 6-10, 17, 19, 20, and 25 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Hergenrother *et al.* in view of Nurton (*Managing Intellectual Property*, 92:73, 1999). The Examiner relies on Hergenrother *et al.* as detailed in section A above, but concedes that this reference does not disclose each feature of the instant claims. The Examiner asserts, however, that Nurton remedies the deficiencies in Hergenrother *et al.*, thereby rendering the instant claims *prima facie* obvious.

C. Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Hergenrother in view of Business Wire (2000). The Examiner relies on Hergenrother *et al.* as detailed in section A above, but concedes that this reference does not disclose each feature of claims 4 and 5. The Examiner asserts, however, the Business Wire remedies the deficiencies in Hergenrother *et al.*, thereby rendering the instant claims *prima facie* obvious.

D. Claims 12 and 18 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Hergenrother in view of Nurton and further in view of Business Wire. The Examiner relies on Hergenrother *et al.* as detailed in section A above, but concedes that this reference does not disclose each feature of claims 12 and 18. The Examiner asserts, however, that Nurton and Business Wire remedy the deficiencies in Hergenrother *et al.*, thereby rendering the instant claims *prima facie* obvious.

Applicant respectfully traverses each of the rejections outlined in sections B-D and submits that the instant claims satisfy the requirements of non-obviousness. Specifically, the cited references in combination not only fail to teach or suggest each feature of the instant claims, but fail to provide any motivation to perform the active, recited steps of the presently claimed process with a reasonable expectation of success, such as identifying an achaogen that is capable of decreasing the rate at which a bacteria mutates, and selling an antibiotic compound with the achaogen. As such, the cited references fail to provide the required elements of a *prima facie* case of obviousness. *See KSR v. Teleflex, Inc.,* No 04-1350 at 4, 14 (U.S. Apr. 30, 2007).

As detailed above, Hergenrother *et al.* fail to teach or suggest each feature of the instant claims, and particular fail to teach or suggest the active, recited step of identifying an achaogen that is capable of decreasing the rate at which a bacteria mutates. Neither Norton nor Business Wire remedy the deficiencies in Hergenrother *et al.*, since neither of these references even remotely teach nor suggest the active, recited step of identifying an achaogen that is capable of decreasing the rate at which a bacteria mutates. Indeed, neither Norton nor Business Wire disclose anything remotely concerned with decreasing the rate of bacterial resistance to an antibiotic. Since the cited references in combination fail to teach or suggest each feature of the instant claims, Applicant submits that these references fail to establish the required elements of a *prima facie* case of obviousness over the presently claimed subject matter.

Given these deficiencies, as detailed herein, Applicant further submits that the cited references in combination fail to provide the requisite motivation and reasonable expectation of success in arriving at the presently claimed process. In particular, since none of the references even remotely suggests the steps of identifying an achaogen that is capable of decreasing the rate at which a bacteria mutates, and selling an antibiotic compound with the achaogen, the Examiner lacks the required technical basis to assert that the presently claimed process is rendered obvious by the combination of references.

Applicant, therefore, submits that the instant dependent claims satisfy the requirements of obviousness over the cited references, and respectfully requests withdrawal of the rejections under 35 U.S.C § 103(a).

Applicant believes that all of the claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Should any issues remain, the Examiner is urged to contact Applicant's undersigned representative.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/Carol D. Laherty/
Carol D. Laherty, Ph.D.
Registration No. 51,909

CDL:jjl

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

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